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EXAMINER
[illegible]

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ART UNIT	PAPER NUMBER
1202	5

DATE MAILED: 07/14/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 5/28/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 4-8, 15, 20 and 23-26 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-3, 9-14, 16-19, 21 and 22 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 4-8, 15, 20 and 23-26 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Applicant's election of I without traverse is acknowledged. The non election has been cancelled. Claims 4-8, 15, 20 and 23-26 are pending.

Claims 4-8, 15, 20 and 23-26 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

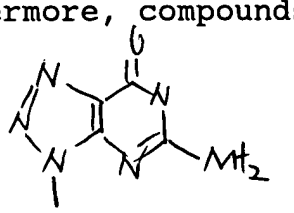
The following reasons apply:

1. "antiviral" is unclear. It reads on any and all viral infections, including AIDS viruses.

2. There is no adequate support that the instant compounds are useful for the urged utility, such as treating retroviruses, AIDS or AID-related diseases. Applicant has provided in vitro test data of two compounds within the instant scope against four viruses and their cytopathogenic effect on HIV. It is well-known that those skilled in the art would not associate successful in vitro results with successful in vivo efficacy. One skilled in the art would not accept the in vitro testing set forth in the present specification as a proper basis to conclude that instantly claimed compounds are useful in in vivo treatment of humans afflicted with retroviral diseases.

Furthermore, the test data (Table I) is not clearly understood. Does applicant intend a range of dosage? It is noted that higher dosage is twice of lower dosage. Since ID_{50} is the minimum drug conc. that inhibits CPE by 50%, the data is of no statistic significance. as for VZV and/or HCMC, the ID_{50} is unclear. What is >96 or >38? 400? 600? 1000? The data further support that antiviral activity is unpredictable. The specification does not commensurate with the scope of the claim. Ex parte Balzarini, 21 USPQ 2d 1892.

Claims 4-8, 15, 20 and 23-26 are rejected under 35 U.S.C. § 101 because although the in vitro testing appears to be useful as a screening tool in order to determine which compounds are candidates for further test to see if they possess in vivo utility. The in vitro tests are not predictive of in vivo efficacy. Furthermore, compounds where R_1 as



are not a purine derivative and is not commonly recognized as the base of the analog of AZT type compound.

As discussed under 112 rejection, antiviral activities are unpredictable . Only two compounds have been in vitro tested. There is no reasonable assurance that claimed compounds have in

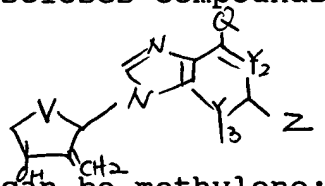
vivo efficacy in the treatment of retroviral diseases broadly or specifically AIDS. Ex parte Balzarini, supra.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 4-8, 15, 20 and 23-26 are rejected under 35 U.S.C. § 102((a) and/or (e)) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over EP '849.

EP discloses compounds of



wherein V can be methylene; Y_2 and Y_3 can independently be nitrogen or CH; Q is NH_2, NHoH, $NHCH_3$ or hydrogen; Z is hydrogen, halo or NH_2, useful in inhibiting AdoMet-dependent transmethylation and in the treatment of patients afflicted with neoplastic or viral diseases. The instantly claimed compounds are taught therein and are obvious thereover in view of the structural similarity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tsang whose telephone number is (703) 308-4715.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CECILIA SHEN
PRIMARY EXAMINER
ART UNIT 122

TSANG:ebw
July 13, 1992